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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,101	05/18/2001	Robert D. Mass	3118/1H146US1	9233

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,101	MASS, ROBERT D.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 24, 2004 has been entered.

2. Claims 21, 25 and 26 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

4. The rejection of claims 21, 25 and 26 under 35 U.S.C. 112, first paragraph, as being indefinite, is withdrawn in view of the amendment to claim 21.

5. The rejection of claim 21 under 35 U.S.C. 112, first paragraph, because the specification failed to enable the full scope of the invention, is withdrawn in view of the amendment to claim 21, limiting the antagonist to a Her2 antibody.

6. The rejection of claim 21 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of the amendment to claim 21.

New Grounds of Rejection:

Claim Rejections - 35 USC § 112

7. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is indefinite because it refers to an antibody "rhuMab 4D5 (Herceptin®)". Does this refer to one specific species of humanized monoclonal 4D5 antibody (rhuMab 4D5-8)? Or, is Herceptin® an example of one possible humanized monoclonal 4D5 antibody.

8. Claims 21, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baselga I (Baselga, Journal of Cinical Oncology, 14: 737-744, 1996; cited in IDS) or Baselga II (Baselga, Semin. Oncol., 26(4): 87-83, 1999) in view of either Pauletti (previously identified as "Godolphin"; Oncogene, 13: 63-72, 1996; of record) or Persons (Annals of Clincial and Laboratory Science, 30: 41-48, 2000, Jan.; cited in IDS).

Claims 21, 25 and 26 are drawn to methods for identifying and treating a patient disposed to respond favorably to a Her2 antibody comprising detetecting Her2 gene amplification in a sample of tumor cells from the patient and treating the patient with Her42 gene amplification with a Her2 antibody.

Either of Baselga I or Baselga II teaches methods for treating breast cancer patients over expressing Her2 with trastuzumab (Herceptin®; rhu-Mab 4D5-8). Therefore, either of Baselga I or Baselga II recognizes that breast cancer patients should be screened for overexpression of Her2 before treatment to find those patients that have the highest likelihood of responding to treatment.

Neither Baselga I nor Baselga II teaches a step of using fluorescent-labeled nucleic acid probes to detect her2 gene amplification (FISH). However, either Pauletti or Persons teaches that detection of Her2 gene amplification using FISH is superior to immunochemistry for assessing Her2 status in patients with breast cancer, and Pauletti teaches that almost all patients that overexpress Her2 as determined by immunocytochemistry do so because of gene amplification. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have altered the detection steps of Baselga I or Baselga II for the purpose of assessing a patient's Her2 status. One would have been motivated to use FISH instead of immunocytochemistry because either Pauletti or Persons teaches the advantages of the FISH technique.

Applicant argues that the claimed inventions are unobvious over the prior art because applicant has discovered a surprising result that patients assessed as overexpressing Her2 because of gene amplification respond better to treatment than patients whose Her2 status is only assessed by immunocytochemistry. This argument is not found persuasive, because the motivation to combine the references does not have to be the same as applicants' motivation for making the claimed inventions.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
September 12, 2004

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
9/14/2004